K122025

OCT 9 2012

510[k] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter Name	KTK Medical Supplies GmbH
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Date summary was prepared	2012–06–25
Device Trade Name(s)	BRIGHTGLASS BRIGHTGLASS M
Classification Name	Temporary Crown and Bridge Resin
C.D.R. section number	872.3770
Product Code	EBG
Regulatory Class	class II
Predicate Devices	K080182 ZENO PMMA Discs
Device Description	BRIGHTGLASS discs are milling blanks composed of hot cured polymethymethacrylate (PMMA). They are intended to be used by dental professionals e.g. dental technicians for the fabrication of long-term temporary crowns and bridgeworks as custom-made restorations for the sole use of a particular patient. These restorations are designed virtually by dental technicians using the CAD technology on the basis of intraoral scans or scans from impressions and/or models. The designed restorations can thereafter be machined in all appropriate CAM Milling Centers out of BRIGHTGLASS Discs. In a further step the milled workpiece can be individually characterized with veneering materials and polished for to improve the aesthetic appearance of the finished restoration.

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BRIGHTGLASS discs are offered as monochromic disc (BRIGHTGLASS) in six different shades and as multicolored disc (BRIGHTGLASS M) in up to four shades, all discs in different thicknesses.

Indications for Use

BRIGHTGLASS Discs are milling blanks consisting of polymethylmethacrylate (PMMA) and designed for the fabrication of long-term temporary crown and bridgework using the CAD/CAM technique.

BRIGHTGLASS Discs are recommended for manufacturing substructures of single tooth crowns and bridgework with up to two pontics.

Summary of technological characteristics / Testing Summary

In order to demonstrate compatibility of BRIGHTGLASS PMMA discs to the predicate devices ZENO PMMA discs a series of testing was performed – in particular tensile strength, elastic limit, bending strength, e-module, water solubility and water absorption. See section 18.

Substantially Equivalence

The information discussed above demonstrates that BRIGHTGLASS PMMA discs are substantially equivalent to the predicate dental device ZENO PMMA Discs.

Both devices are polymethylmethacrylates (PMMA).

Both devices have identical indications for use.

Both devices have comparable technical, physical, chemical, and biological properties and characteristics.

Both devices have the same aesthetic, prophylactic and diagnostic function.

The thermoplastic manufactured BRIGHTGLASS disks shows like the predicate device an extreme high homogeneity and by the high surface density a major bending strength and breaking resistance.

BRIGHTGLASS discs are as safe, as effective and performs as well than the predicate device.

Conclusion

The information discussed above demonstrates that the BRIGHTGLASS discs are substantially equivalent to the predicate devices.

Declaration

This summary includes only information that is also covered in the body of the 510(k).

This summary does not contain any puffery or unsubstantiated labeling claims.

This summary does not contain any raw data, i.e., contains only summary data.

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This summary does not contain any trade secret or confidential commercial information

This summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KTK Medical Supplies GmbH
Mr. Thomas Lottermoser
Chief Executive Officer
Industriestr. 16
82110 Germering, Germany

OCT 9 2012

Re: K122025
Trade/Device Name: Brightglass, Brightglass M
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: September 6, 2012
Received: September 6, 2012

Dear Mr. Lottermoser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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KTK Medical Supplies

Indications for Use

510(k) Number (if known): K122025

Device Name: BRIGHTGLASS

Indications For Use:

BRIGHTGLASS Discs are milling blanks consisting of Polymethylmethacrylate (PMMA) and designed for the fabrication of long-term temporary crown and bridgework. They are machined with the CAD/CAM technique.

BRIGHTGLASS Discs are recommended for manufacturing substructures of single tooth crowns and bridgework with up to two pontics.

Susan Runz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122025

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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